REMARKS

The present application is a continuation prosecution application (CPA) of U.S. Patent Application 08/812,616 (the parent application), filed March 6, 1997, now abandoned. The parent application was subjected to a restriction requirement mailed 3/31/98. The applicants responded to the restriction requirement on 4/27/98. The USPTO, in an Office Action dated 7/22/98 made final the restriction requirement and indicated its decision to examine claims 1-23, 53-81, and 120. Claims 24-52 and 82-119 were withdrawn from consideration as being drawn to non-elected subject matter. The Office Action also rejected claims 1-9, 11-14, 16-22, 53-61, 63-68, 70-78, 80, 81, and 120 and objected to claims 10, 15, 23, 62, 69 and 79 dependent upon a rejected base claim but indicated they would be allowable in rewritten in independent form including all of the limitations of the base claim and any intervening claim. On 8/31/98, Applicants filed a Supplemental IDS, citing new art from the PCT International Search Report that was not of record. Applicants did not receive from the Examiner an initialed PTO-1449, indicating that the newly cited art was made of record. **Applicants respectfully request acknowledgment from the Examiner that the newly cited indicated in the supplemental IDS filed on 8/31/98 has been made of record.** Applicants filed the present CPA on 1/21/99.

This preliminary amendment cancels claims drawn to the non-elected subject matter in the parent application, amends other claims, and adds new claims in view of the Office Action of 7/22/98 in the parent case in order to place this case in condition for allowance. Amendment of the claims herein should not be construed as abandonment of any cancelled subject matter. All of the amendments and the new claims are fully supported by the specification as filed and no new matter has been added. After entry of the present amendments, the following claims should be pending: 1, 4-23, 53, 56-63, 65-81, and 120-143. These claims are attached as an appendix.

I. Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 8, 58, 64, and 71 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regards as the invention. This rejection is overcome by the present amendment to these claims.

In claim 8, the words "an ligand" has been amended to --a ligand-- to make the language grammatically correct.

To correct claim dependency, claims 58 and 71 have been amended to refer to appropriate previous claims.

Claim 64 was rejected for lack of alleged antecedent support. This claims has now been canceled and new claims 121 and 122 have been added to correct this problem. Claim 122 now has the proper antecedent support for recitations of "the ligand" and "the receptor" in claim 121.

II. Rejection Under 35 U.S.C. §102

Clin. Chem. 39/4, 619-624, 1993 ["Lou"]

Claims 1, 2, 5, 6, 13, 14, 53, 54, and 58 were rejected under 35 U.S.C. 102(b) as being anticipated by the Journal article "One-Step Competitive Immunochromatographic Assay for Semiquantitative Determination of Lipoprotein(a) in Plasma" by Lou et al; Clin. Chem. 39/4, 619-624 (1993) [hereinafter "Lou"]. This rejection is overcome by the present amendment to these claims as outlined above.

Lou discloses a method of chromatographic test strip for detection and quantification of lipoprotein a (Lp(a)). As shown in Fig. 1, page 620 of Lou, the test strip comprises a sample loading area, conjugate pad, measurement region, and an end of assay indicator. The conjugate pad contains diffusible Lp(a) coated colloidal selenium, which provides an easily visible result owing to its rust color. The measurement region contains immobilized monoclonal antibodies specific for Lp(a). The antibodies are positioned in the measurement region in a ladder-bar format. An end of assay indicator is located at the end of the test strip. In use, the number of ladder bars shown in the measurement region provides an indication of the amount of Lp(a) present.

Lou does not however, teach or suggest the presently claimed method of and device for visually quantifying an amount of an analyte in a sample, where the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte. Amended claims 1, 5, 6, 13, 14, 53, and 58 now specify that the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte. These claims therefore exclude from their scope a diffusively bound labeled first sbp member that is analogous to the analyte. The rejection of these claims under 35 U.S.C. 102(b) as being anticipated by Lou et al. should therefore be withdrawn.

III. Rejection Under 35 U.S.C. §103

Lou in view of Maggio

The Examiner has rejected claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 under 35 U.S.C. 103(a) as being unpatentable over Lou in view of Enzyme-Immunoassay, Edward T. Maggio, Ed., pp 61, 184-185 [Hereinafter "Maggio"]. This rejection is respectfully traversed.

Maggio teaches the advantages and disadvantages of various methods of enzyme immunoassay (page 61). For effective competitive assays, the antigen used for labeling should be as pure as possible (page 184). However, for the sandwich methods where antibody is labeled, it is not always necessary for the antibody to be highly purified (page 184).

According to the Examiner, it would have been obvious to one of ordinary skill in the art to configure the test strip of Lou for sandwich immunoassays as taught by Maggio because Maggio teaches that sandwich immunoassays provide the advantage of obviating the need for an antigen reagent, such as the Lp(a) required for the Lp(a) coated selenium particles in the conjugate pad of Lou et al. By configuring the test strip of Lou for a sandwich immunoassay, there would be no need for purification procedures to obtain highly purified Lp(a).

Furthermore, according to the Examiner, with respect to claim 120, it would have been obvious to one of ordinary skill in the art to place the test strip of Lou (or Lou as modified by the teachings of Maggio) in a test kit arrangement because test kits are well known in the art for their recognized advantages of convenience and economy.

The Applicants respectfully disagree with the position taken by the Examiner. To establish a *prima facie* case of obviousness under 35 U.S.C. §103, three basic criteria must be

met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2142-2143 (7th Ed. 1997). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicants' disclosure. MPEP §2142-2143. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

In the present case, the Applicants respectfully submit that the Examiner has not established the three criteria required for a *prima facie* case of obviousness for any of the rejected claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120.

The Applicants respectfully submit that there is no teaching, suggestion, or motivation found in the prior art to combine the reference teachings because *the proposed modification renders the prior art invention unsatisfactory for its intended purpose*. MPEP §2143.01. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). The invention in Lou is a "*one step* competitive immunochromatographic assay to measure Lp(a) plasma" (page 619, first introductory paragraph; emphasis added). This one step assay is deemed very significant because the other prior art methods described in Lou "require either *multi-step procedures* or a long assay time" (page 619, 2nd column;). On the other hand, the sandwich method described in Maggio requires *two wash steps*. Clearly the sandwich method disclosed in Maggio is not a one step procedure or assay. Modifying Lou to configure the test strip of Lou for sandwich immunoassays as suggested by the Examiner would clearly frustrate the intended purpose of Lou to carry out a rapid, one-step, non-instrumented competitive immunochromatographic method. For this reason, Lou cannot be combined with Maggio.

Combining Maggio with Lou also *teaches away from* the present invention since the purpose of the Applicants' invention is to provide simple, one-step solid phase non-instrumented methods and devices for quantitating an analyte in a sample suspected of containing the analyte. Other assay techniques employing a multiplicity of steps, such as wash steps are undesirable (see Specification, page 2, lines 28-38). For this reason, Lou cannot be combined with Maggio to arrive at the present invention. The rejection of claims 4, 8, 11, 16-

19, 21, 22, 56-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 under 35 U.S.C. 103(a) as being obvious over Lou in view of Maggio should therefore be withdrawn.

Lou in view of Weng

The Examiner has rejected claim 7 under 35 U.S.C. 103(a) as being unpatentable over Lou in view of U.S. Patent 4,740, 468 issued to Weng et al. [hereinafter "Weng"]. This rejection is overcome by the amendment to claim 1 from which claim 7 depends.

Weng has been cited by the Examiner for its alleged teaching of the use of particles to indirectly immobilize antibodies to a specific reagent zone of a chromatographic test strip. However since neither Lou nor Weng teaches or suggests the use of a diffusively bound labeled first sbp member that is complementary to the analyte, Lou and Weng cannot be combined to arrive at the present invention. The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Lou in view of Weng should therefore be withdrawn.

Lou in view of Maggio, and further in view of Weng

The Examiner has rejected claims 20, 59, and 76 under 35 U.S.C. 103(a) as being unpatentable over Lou in view of Maggio as applied to claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 above, and further in view of Weng. This rejection is respectfully traversed in view the arguments above that were used to traverse the rejection of claims 4, 8, 11, 16-19, 21, 22, 56-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 over Lou in view of Maggio.

Regardless of the teaching of Weng, since Lou and Maggio cannot be combined for reasons discussed above, it follows that Lou, Maggio and Weng also cannot be combined together to reject claims 20, 59, and 76. The rejection of these claims under 35 U.S.C. 103(a) as being unpatentable over Lou in view of Maggio and further in view of Weng should therefore be withdrawn.

Lou in view of Maggio, and further in view of Kang

The Examiner has rejected claims 71 and 81 under 35 U.S.C. 103(a) as being unpatentable over Lou in view of Maggio as applied to claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 above, and further in view of U.S. Patent

5,559,041 issued to Kang et al. [Hereinafter "Kang"]. Kang has been cited for the alleged disclosure of a multizone chromatographic test strip for performing sandwich or competitive immunoassays wherein multiple test strips are configured around a common sample receiving zone for the purpose of assaying one or more analytes in a given sample. This rejection is respectfully traversed in view of the arguments above that were used to traverse the rejection of claims 4, 8, 11, 16-19, 21, 22, 56-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 over Lou in view of Maggio.

Regardless of the teaching of Kang, since Lou and Maggio cannot be combined for reasons discussed above, it follows that Lou, Maggio and Kang also cannot be combined together to reject claims 71 and 81. The rejection of these claims under 35 U.S.C. 103(a) as being unpatentable over Lou in view of Maggio and further in view of Kang should therefore be withdrawn.

Lou in view of Katz

The Examiner has rejected claim 9 under 35 U.S.C. 103(a) as being unpatentable over Lou in view of U.S. Patent 4,496,654 issued to Katz et al. [Hereinafter "Katz"]. Katz has been cited for the alleged teaching of the use of an avidin/biotin system for immobilizing antibodies to a solid support. This rejection is overcome by the amendment to claim 1 from which claim 9 depends.

Since neither Lou nor Katz teaches or suggests the use of a diffusively bound labeled first sbp member that is complementary to the analyte, Lou and Weng cannot be combined to arrive at the present invention. The rejection of claim 9 under 35 U.S.C. 103(a) over Lou in view of Katz should therefore be withdrawn.

Lou in view of Maggio and further in view of Katz

The Examiner has rejected claim 61 under 35 U.S.C. 103(a) as being unpatentable over Lou in view of Maggio as applied to claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 above, and further in view of Katz. This rejection is respectfully traversed in view the arguments above that were used to traverse the rejection of claims 4, 8, 11, 16-19, 21, 22, 56-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 over Lou in view of Maggio.

Regardless of the teaching of Katz, since Lou and Maggio cannot be combined for reasons discussed above, it follows that Lou, Maggio and Katz also cannot be combined together to reject claim 61. The rejection of this claim under 35 U.S.C. 103(a) as being unpatentable over Lou in view of Maggio and further in view of Katz should therefore be withdrawn.

Lou in view of Bunting

The Examiner has rejected claims 9 and 12 under 35 U.S.C. 103(a) as being unpatentable in view of U.S. Patent 4,271,140 issued to Bunting [Hereinafter "Bunting"]. Bunting has been cited for its alleged teaching of the use of a receptor/hapten system for immobilizing antibodies to a solid support. This rejection is overcome in view of the amendment to claim 1 from which claims 9 and 12 depend.

Since neither Lou nor Bunting teaches or suggests the use of a diffusively bound labeled first sbp member that is complementary to the analyte, Lou and Weng cannot be combined to arrive at the present invention. The rejection of claims 9 and 12 under 35 U.S.C. 103(a) over Lou in view of Bunting should therefore be withdrawn.

Lou in view of Maggio, and further in view of Bunting

The Examiner has rejected claim 64 under 35 U.S.C. 103(a) as being unpatentable over Lou in view of Maggio as applied to claims 3, 4,8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 above, and further in view of Bunting. Claim 64 has now been canceled, but the subject matter of this claim is now embodied in claims 121-122. This rejection is respectfully traversed in view the arguments above that were used to traverse the rejection of claims 3, 4, 8, 11, 16-19, 21, 22, 55-57, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120 over Lou in view of Maggio.

Regardless of the teaching of Bunting, since Lou and Maggio cannot be combined for reasons discussed above, it follows that Lou, Maggio and Bunting also cannot be combined together to reject claims 121-122. The rejection of these claims under 35 U.S.C. 103(a) as being unpatentable over Lou in view of Maggio and further in view of Bunting should therefore be withdrawn.

III. Allowable Subject Matter

In the Office Action mailed 7/22/98 (paper number 7), the Examiner objected to claims 10, 15, 23, 62, 69, and 79 as being dependent upon a rejected base claim, but indicated that they would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The Applicants thanks the Examiner for indicating this allowable subject matter. These claims have now been presented in independent form and should be allowed.

IV. The New Claims 123-143

Part of the subject matter of the original claims are now embodied in new claims 123-134. Claims 123 -130 are drawn to a method and claims 131-143 to a device for determining an amount of an analyte in a sample. In these claims, the first sbp member is specified to be analogous to the analyte. These claims are distinct from the disclosure of Lou in that they specify that the particulated label of the first sbp member comprises dyed latex beads, erythrocytes, liposomes, dyes sols, metallic colloids, or stained microorganisms. Lou, on the other hand employs a nonmetallic colloid (colloidal selenium) as a label, which provides an easily visible result owing to its rust color. Nonmetallic colloids are thus specifically excluded from the scope of these new claims.

Conclusion

Applicants believe they have now, through this amendment, responded completely to the Office Action mailed September 1, 2000. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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Appendix of Pending Claims

1. A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample.

4. The method of claim 1, wherein the labeled first sbp member is an antiligand capable of binding the analyte.

5. The method of claim 1, wherein the first sbp member includes a visually detectable label.

6. The method of claim 5, wherein the visually detectable label comprises a visible particulate label.

7. The method of claim 1, wherein the second sbp member is attached to particles and the particles are immobilized in the capture zones.

8. The method of claim 1, wherein the second spb member is a ligand capable of binding the analyte.

9. The method of claim 1, wherein the second sbp member is labelled with a ligand and is immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone.

10. (Amended) A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein the second sbp member is an antibody against a complex formed between the analyte and the first sbp member.

11. The method of claim 1, wherein the analyte is a polyepitopic molecule and the first and second sbp members are antibodies against different epitopes of the analyte.

12. The method of claim 9, wherein the ligand is a hapten and the receptor is a complement to the hapten.

13. The method of claim 1, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones, and the step of observing a pattern of label that accumulates at the one or more capture zones comprises determining a number of capture zones at which label accumulates.

14. The method of claim 1, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone and the step of observing a pattern of labeled first sbp member that accumulates at the one or more capture zones comprises observing a distance traversed by the label along the single capture zone.

15. (Amended) A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

16. A method of determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture

zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of labeled first sbp member that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample.

17. The method of claim 16, wherein the labelled first spb member is a antibody capable of binding the analyte.

18. The method of claim 16, wherein the labelled first sbp member includes a visually detectable label.

19. The method of claim 18, wherein the visually detectable label comprises a visible particulate label.

20. The method of claim 16, wherein the second sbp member is attached to particles and the particles are immobilized in the one or more capture zones.

21. The method of claim 18, wherein the lateral flow matrix comprises a plurality of capture zones, and the step of observing a pattern of label that accumulates at the one or more capture zones comprises determining a number of capture zones at which label accumulates.

22. The method of claim 18, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone and the step of observing a pattern of labeled first sbp member that accumulates at the one or

more capture zones comprises observing a distance traversed by the label along the single capture zone.

23. (Amended) A method of determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of labeled first sbp member that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein the labeled first sbp member includes a visually detectable label;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

53. A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a

second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte.

56. (Amended) The device of claim 53, wherein the labeled first sbp member is an antibody capable of binding the analyte.

57. (Amended) The device of claim 53, wherein the first sbp member includes a visually detectable label.

58. The device of claim 57, wherein the visually detectable label comprises a visible particulate label.

59. The device of claim 53, wherein the second sbp member is attached to particles and the particles are immobilized in the capture zones.

60. The device of claim 53, wherein the second spb member is an antibody capable of binding the analyte.

61. The device of claim 53, wherein the second sbp member is labelled with a ligand and is immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone.

62. (Amended) A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more

capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

wherein the second sbp member is an antibody against a complex formed between the analyte and the first sbp member.

63. The device of claim 55, wherein the analyte is a polyepitopic molecule and the first and second sbp members are antibodies against different epitopes of the analyte.

65. The device of claim 53, wherein the analyte is human IgE.

66. The device of claim 65, wherein the first sbp member is goat anti-human IgE and the second sbp member is mouse monoclonal anti-human IgE.

67. The device of claim 53, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones.

68. The device of claim 53, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

69. (Amended) A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

70. The device of claim 53, wherein the device comprises a plurality of discrete lateral flow matrices.

71. The device of claim 70, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.

72. A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the device comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte.

73. The device of claim 72, wherein the labelled first spb member is an antibody capable of binding the analyte.

74. The device of claim 72, wherein the labelled first sbp member includes a visually detectable label.

75. The device of claim 74, wherein the visually detectable label comprises a visible particulate label.

76. The device of claim 72, wherein the second sbp member is attached to particles and the particles are immobilized in the one or more capture zones.

77. The device of claim 72, wherein the lateral flow matrix comprises a plurality of capture zones.

78. The device of claim 72, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

79. (Amended) A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the device comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

80. The device of claim 72, wherein the device comprises a plurality of discrete lateral flow matrices.

81. The device of claim 80, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.

120. (Amended) A kit for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising the device of any one of claims 53 or 74, a chart for correlating an observed accumulation of label at the one or more capture zones, to a concentration of analyte in a sample applied to the sample receiving zone, and instructions for using the device.

121 (New). The device of claim 53, wherein the first sbp member is a ligand and the second sbp member is a receptor complementary to the ligand.--

122 (New). The device of claim 121 wherein the ligand is a hapten and the receptor is a complement to the hapten.

123 (New). A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein said first sbp member includes a visually detectable particulate or nonparticulate label, said particulate label comprising dyed latex beads, erythrocytes, liposomes, dyes sols, metallic colloids, or stained microorganisms.

124. (New) The method of claim 123, wherein the second sbp member is attached to particles and the particles are immobilized in the capture zones.

125. (New) The method of claim 123, wherein the second spb member is a ligand capable of binding the analyte.

126. (New) The method of claim 123, wherein the second sbp member is labelled with a ligand and is immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone.

127. (New) The method of claim 123, wherein the analyte is a polyepitopic molecule and the first and second sbp members are antibodies against different epitopes of the analyte.

128. (New) The method of claim 126, wherein the ligand is a hapten and the receptor is a complement to the hapten.

129. (New) The method of claim 123, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones, and the step of observing a pattern of label that accumulates at the one or more capture zones comprises determining a number of capture zones at which label accumulates.

130. (New) The method of claim 123, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone and the step of observing a pattern of labeled first sbp member that accumulates at the one or more capture zones comprises observing a distance traversed by the label along the single capture zone.

131. (New). A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

wherein said first sbp member includes a visually detectable particulate or nonparticulate label, said particulate label comprising dyed latex beads, erythrocytes, liposomes, dyes sols, metallic colloids, or stained microorganisms.

132. (New) The device of claim 131, wherein the second sbp member is attached to particles and the particles are immobilized in the capture zones.

133. (New) The device of claim 131, wherein the second spb member is an antibody capable of binding the analyte.

134. (New) The device of claim 131, wherein the second sbp member is labelled with a ligand and is immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone.

135. (New). The device of claim 131, wherein the second spb member is an antibody capable of binding the analyte.

136. (New) The device of claim 131 wherein the first sbp member is a ligand and the second sbp member is a receptor complementary to the ligand.

137. (New) The device of claim 138 wherein the ligand is a hapten and the receptor is a complement to the hapten.

138. (New) The device of claim 131, wherein the analyte is human IgE.

139. (New) The device of claim 131, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones.

140. (New) The device of claim 131, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

141. (New) The device of claim 131, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

142. (New) The device of claim 131, wherein the device comprises a plurality of discrete lateral flow matrices.

143. (New) The device of claim 142, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.